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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,179	11/06/2001	Sean A. McCarthy	MBIO97-018DVIACN1M	1059

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MILLENNIUM PHARMACEUTICALS, INC.
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CAMBRIDGE, MA 02139

EXAMINER

LAMBERTSON, DAVID A

ART UNIT PAPER NUMBER

1636

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/993,179

Applicant(s)

MCCARTHY ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II (claims 18-25 with respect to SEQ ID NO: 3/4) in the reply filed on May 13, 2004 is acknowledged.

Claims 18-25 are pending in the application, and are being examined with respect to a protein encoded by SEQ ID NO: 3 or represented by SEQ ID NO: 4.

Priority

Applicant's claim for domestic priority to US Application 09/436,183 (US Patent 6,410,315) and 08/966,269 (US Patent 6,046,000) under 35 U.S.C. § 120 is acknowledged.

Claim Objections

Claims 18-25 are objected to because of the following informalities: claims 18-25 refer to non-elected subject matter, specifically a protein encoded by SEQ ID NO: 1 or represented by SEQ ID NO: 2. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 18-25 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. Claims 18-25 are directed to a protein encoded by SEQ ID NO: 3, or

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represented by SEQ ID NO: 4. The protein is named emxosb4f08, and is indicated to have a region of 44 amino acids (residues 64-108) that are identical to a stretch of amino acids in a putative calcium-binding protein (EMBL Accession No. JS0027) (see for Example pages 25-26, the bridging paragraph, of the instant specification). However, it is noted that there is no determination of a biological activity associated with emxosb4f08. It is unknown if it performs the same activity as JS0027; indeed because at the time of filing JS0027 was only a putative calcium binding protein, the activity of the protein to which homology is indicated is also unknown. In other words, there was no function associated with either the claimed protein or the protein to which it has homology at the time of filing. Since there is no function associated with the protein, the protein has no utility and does not meet the standards of 35 USC § 101.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-25 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

As such, claims 18-25 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

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The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), and the most relevant factors are indicated below:

Nature of the invention. The nature of the invention is a polypeptide, emxsob4f08. In order for the skilled artisan to be able to use the claimed invention, emxsob4f08 must have a functional activity that has a use. In the instant case, the activity is predicated based upon the homology of emxsob4f08 to a putative calcium-binding protein with the EMBL Accession number JS0027.

State of the art. The state of the art at the time of filing is silent both with regard to the actual activity of JS0027 and the instantly claimed protein emxsob4f08. Thus the skilled artisan cannot rely on the teachings of the prior art to ascertain how to use the specifically claimed invention.

Even if the activity of JS0027 were known in the art, the invention as claimed would still be unpredictable because it is based upon conservation of activity based upon homology alone.

The prediction of function based on sequence homology is an unpredictable art. This was demonstrated by the conflicting publications of Scott *et al.* (*Nature Genetics* **21**: 440-443, 1999; see entire document; henceforth Scott) and Everett *et al.* (*Nature Genetics* **17**: 411-422, 1997; see entire document; henceforth Everett) regarding the cloning and characterization of PDS.

Everett initially identified and sequenced the protein, predicting based upon the sequence that the PDS gene product functioned as a sulphate ion transporter protein because of its similarity to a

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family of known sulphate ion transporters (see for example the Abstract and page 419, right column, second full paragraph). However, further characterization done by Scott indicated that PDS was not a sulphate ion transporter because it was unable to transport sulphate ions; rather, Scott identified that PDS was a chloride and iodide ion transporter (see for example the Abstract and page 440, the paragraph bridging the left and right columns to the second full paragraph). Scott further indicated that their results underscored the importance of establishing function even in the face of significant homology to proteins of known function (see for example page 441, left column, third full paragraph), thereby establishing that function based on homology is an unpredictable endeavor. Thus, the teachings of the State of the Art indicate the unpredictability of the claimed invention.

Number of working examples and Guidance provided by applicant. The instant specification does not provide sufficient teachings to overcome the deficiencies regarding the claimed invention in the State of the Art at the time of filing. The instant specification simply identifies a region of homology between the instantly claimed protein and a protein with only a putative function. There is no demonstration that either protein has the putative activity, let alone a demonstration that the conserved region between the two proteins is necessary and sufficient for maintaining the claimed activity. As a result, the invention remains unpredictable with regard to both the teachings of the Art and the instant specification.

Unpredictability of the art and Amount of experimentation required. The instantly claimed invention is highly unpredictable for two reasons: first, the instant specification does not identify an activity for the claimed protein (emxosfb408), presuming a conservation of activity between said protein and a protein with a putative function (JS0027); second, even if JS0027 had a known

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activity, there is no demonstration that the region of homology between JS0027 and emxosb4f08 is necessary and sufficient for the presumed activity, and predicting function based solely on degrees of homology has been shown in the State of the Art to be highly unpredictable. Thus, in order to practice the claimed invention, the skilled artisan would be required to complete the instant invention by identifying the activity of the claimed protein. This requires a great deal of undue and unpredictable trial and error experimentation on the part of the skilled artisan. As such the claimed invention does not meet the standards of 35 USC § 112, first paragraph, and lacks enablement.

Allowable Subject Matter

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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JAMES KETTER
PRIMARY EXAMINER